Purpose: To document a patient's post-transplant long-term medical status.
The initial follow-up, to be done on the anniversary date of the last transplant performed during the operational phase of the LTD, will capture all information since the last complete follow-up during the operational phase of the LTD.

Amendment: *According to the revised protocol (January 2001), a one-time clinical follow-up (instead of yearly follow-up) will be completed for each patient by the end of the data collection period for the study (December 31, 2002), covering a period of at least 7 years since the last transplant during the operational phase of the LTD (prior to July, 1995). However, if a patient has already been evaluated prior to January 2001 but the evaluation period does not cover a 7 year post-transplant period, an additional follow-up should be completed to update the information.*

If the patient received a retransplant or died since the last complete follow-up evaluation during the operational phase of the LTD, this follow-up evaluation should be completed to capture information up to the time of retransplantation or death. If both of these events occurred, a follow-up evaluation should be completed to capture information to the time of retransplantation only, and a death form (MD) should be completed to document mortality information. If a patient received a retransplant, no further LT forms are to be completed after the one documenting patient status up to the time of retransplantation.

If the patient receives a retransplant or dies subsequent to completion of an initial follow-up, then an additional evaluation will be completed from the time of the last evaluation up to the point of re-transplant or death. The procedure to be followed will be the same as for the initial follow-up, applied to the appropriate evaluation period (re-transplant or death).

Person(s) Responsible: LTD Clinical Coordinator.
Source(s) of Information: Patient, physician(s) caring for patient, medical chart, and laboratory test reports.
General Instructions: This form is to be completed at least 7 years after the last LTD transplant. The source of information depends upon the location of the patient at the time of the evaluation:

1) Patient at the LTD clinical center - information may be obtained from the hospital charts, laboratory test reports, and by an interview with the patient.
2) Patient at home - information may be obtained from the local physician by phone or mail contact, from the patient or members of the patient's family by phone, and from laboratory reports sent to the LTD clinical center.

Information on patient status should be as current as possible (i.e., on or before the day of evaluation). Laboratory data should reflect results from samples drawn closest to the specified evaluation timepoint. All other information pertains to the time interval since the last evaluation timepoint. For the initial follow-up, the last evaluation is the date of the last MF form during the operational phase of the LTD.

Completion Log:

1) Data Collector ID - Record the two-digit clinical center identification code number and the data collector's three initials (first letter of first, middle, and last names).
2) Data Collection Date – Record the date (month/day/year) on which the form is considered to be accurate and complete.

PATIENT ID

This is the identification number assigned to the patient upon entry into the LTD.

Completing Form: Record the clinical center identification code number before the hyphen, and the assigned 7 digit patient identification number after the hyphen. The patient ID should be recorded on the cover sheet and at the top of each page in the spaces provided.

I.1 EVALUATION TIMEPOINT

The patient will be evaluated at least 7 years post last transplant during the operational phase of the LTD, or at the time of death or retransplantation. Subsequent evaluation will be done only if patient receives re-transplant or dies after the initial evaluation.

Completing Form: Check the appropriate evaluation timepoint. If retransplantation occurs, record the date (month/day/year) of retransplantation. If death occurs, record the date (month/day/year) of death and complete the MD (Death) form. In the event of retransplantation or death, if the liver was excised, autopsied, and pathologic/histologic information is available, complete the pathology forms (PP and PG). If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99).

I.2 IS THERE ANY NEW INFORMATION ON THIS PATIENT SINCE THE LAST EVALUATION?

Document whether any new information on the patient is available since the previous evaluation period. If no new information is available, specify the reason and do not complete the remainder of the form.

Completing Form: Check "Yes" if new information on the patient is available and continue with form completion. Check "No" if no new information is available via patient clinic visit, phone interview, medical chart, physician contact, etc. If there is no new information, specify the reason in the space provided (e.g., lost to follow-up) and do not complete the remainder of the form. Note: specification is limited to 30 characters.

I.3 METHOD OF EVALUATION

Document ALL the sources used to collect patient information and to complete the form during this evaluation period.

Completing Form: Check all the evaluation methods that are used to complete this form. If a telephone interview was conducted with a person other than the patient, specify that person's relationship to the patient (e.g., parent, spouse, physician, etc.). If a method other than those listed is used, specify in the space provided. Note: specification is limited to 30 characters.

I.4 DATE OF LATEST CONTACT/INFORMATION DURING THIS EVALUATION PERIOD

This is the date of the most recent patient contact or most recent patient information obtained from all sources (i.e., methods of evaluation). The date recorded should be within this evaluation period. ***If the patient received a liver retransplant or died, the date of latest contact/info must be identical to the date of retransplantation or death. Retransplantation and death are patient censoring endpoints, therefore date of latest contact/info cannot be after those dates.***

Completing Form: Record the date (month/day/year) of the most recent patient contact or most recently obtained patient information. In the event of retransplantation or death, record the date of the appropriate event as the date of latest contact/information. If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99).

I.5 PATIENT STATUS

Information on patient status should be as current as possible (i.e., on or before the day of evaluation).

I.5.1 KARNOFSKY SCALE

The Karnofsky scale rates the patient's level of activity as assessed by the clinical coordinator. However, if the patient does not return to the LTD clinical center for evaluation, the coordinator must rely on the patient or local physician to provide this information. In cases where a chart review is the only source of information, the coordinator may base the assessment on chart entries over the past six months. For the purpose of this database, phrases have been incorporated that will enable the evaluation of children as well.

1. Normal, no complaints, no evidence of disease. This patient does not look or act like he/she has liver disease and, in the case of adults, admittedly feels fine.

2. Able to carry on normal activity, minor signs or symptoms of disease. This patient is physically well enough to work or attend school and/or play normally in spite of slight or intermittent evidence of disease (e.g., fatigue).

3. Normal activity with effort, some signs or symptoms of disease. This patient is physically well enough to work or attend school and/or play normally but chronically does not feel well (e.g., chronic fatigue, chronic pruritus).

4. Cares for self (consistent with age) but unable to carry on normal activity or do active work or attend school and/or play. This patient has had to quit usual work duties (in or outside of the home). This student can no longer attend school. This child's play is more passive than active at this point.

5. Requires occasional assistance (beyond general age-appropriate level) but is able to care for most of own needs. This adult (or older child) experiences periods of time when activities of daily living are not possible for him/her to accomplish (appropriate for age). This is the younger child who usually can walk or sit by him- or herself but periodically cannot do this independently.

6. Requires considerable assistance and frequent medical care. This patient can, at best, only assist with activities of daily living appropriate for age. This is the infant who now needs considerable help with feedings that formerly had been easy. This patient also has need of frequent clinic and/or hospital visits for management of signs/symptoms of end-stage disease (e.g., recurrent cholangitis, encephalopathy, chronic unrelieved pruritus, ascites that is difficult to manage, etc.).

7. Disabled, requires special care and assistance. This patient requires total care of most of his/her needs including specialized needs which might include: hemodialysis, tube feeding, home hyperalimentation, etc.

8. Severely disabled, hospitalization is indicated although death not imminent. This patient is not well enough to be managed safely or completely at home any longer.

9. Hospitalization necessary, very sick, active support treatment necessary. Constant medical and/or surgical intervention is needed to keep patient alive such as:

    - FFP infusions/exchange transfusions to control coagulopathy.
    - Frequent infections requiring one or more antibiotics.
    - Treatment of variceal bleeds.
    - May or may not need ventilator assistance but probably requires O_2.

10. Moribund, fatal processes progressing rapidly. May include the following: multiple infections, hepatic coma, active bleeding, and labile BP requiring vasopressors.

Completing Form: Refer to the "Karnofsky Scale" code list on the page opposite the question and record the code number that best describes the patient's level of activity. Record the date (month/day/year) that the score was obtained. If the score was determined via chart review, use the date of the latest contributing piece of information. If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99).

I.5.2 HEIGHT

The height of the patient should be measured.

Completing Form: Record the patient's height in centimeters and the date (month/day/year) that the measurement was obtained. If height is in feet/inches, convert to inches, and then to centimeters by multiplying the height in inches by 2.54 (e.g., cm = inches × 2.54). If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99). If height is not documented, and there is reason to believe that growth has occurred (e.g., pediatrics), a phone call may be made to the patient to obtain this information. If height is not available, record UNK for unknown.

I.5.3 WEIGHT

The weight of the patient should be measured.

Completing Form: Record the patient's weight in kilograms and the date (month/day/year) that the measurement was obtained. If weight is in pounds, convert to kilograms by dividing the weight in pounds by 2.2 (e.g., kg = lbs ÷ 2.2). If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99). If weight is not documented, a phone call may be made to the patient to obtain this information. If weight is not available, record UNK for unknown.

I.5.4 BLOOD PRESSURE

The systolic and diastolic blood pressure should be measured.

Completing Form: Record the patient's blood pressure and the date (month/day/year) that the measurement was obtained. If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99).

I.5.5 IS THE PATIENT CURRENTLY ON HYPERTENSION MEDICATION?

Document the patient's use of medication to control hypertension at the time of this evaluation.

Completing Form: Check "Yes" if the patient is currently taking medication to control high blood pressure. Check "No" if the patient is not currently taking medication to control high blood pressure.

I.6 EVER DRINK ALCOHOL SINCE LAST FOLLOW-UP EVALUATION?

Document the patient's consumption of any type of alcoholic beverage at any time since the previous follow-up evaluation.

Completing Form: Check "Yes" if the patient has consumed any type of alcohol since the previous follow-up evaluation. Check "No" if the patient has not consumed any alcohol. Check UNK if it is unknown whether or not the patient has consumed alcohol.

I.6.1 CURRENTLY DRINK?

If the patient has consumed alcohol at any time since the previous follow-up evaluation, document whether he/she is currently drinking any type of alcoholic beverages and the number of drinks in a typical week. If the patient is not currently drinking, document when the last alcoholic beverage was consumed.

Completing Form: Check "Yes" if the patient is currently drinking any type of alcoholic beverage(s) and record the total number of any and all alcoholic drinks consumed in a typical week (one drink = one 12 oz. beer = one 6 oz. glass of wine = one 1 oz. of hard liquor). If "Yes" to currently drinking, but if the patient does not consume any alcohol during a typical week, record "0" for the number of drinks in a typical week. Check "No" if the patient is not currently drinking alcohol and record the month and year during which the last alcoholic drink was consumed. If any part of the date is unknown, record UNK in that position (e.g., unk/99).

I.6.2 HAS PATIENT EVER THOUGHT OR BEEN TOLD THAT HE/SHE MAY HAVE A DRINKING PROBLEM?

If the patient has consumed alcohol at any time since the previous follow-up evaluation, document whether he/she ever thought or had been told that he/she may have a drinking problem.

Completing Form: Check "Yes" if the patient ever thought or had been told that he/she may have a drinking problem. Check "No" if the patient has never thought or never been told that he/she may have a drinking problem. Check UNK if the information is unknown.

I.7 NUMBER OF BIOPSIES DONE AT THIS EVALUATION OR SINCE THE LAST EVALUATION

Document any and all liver biopsies that were done at the time of this evaluation or since the previous evaluation period.

Completing Form: Record the number of liver biopsies that were done since the previous evaluation and record the date(s) (month/day/year) of each biopsy. If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99). If no biopsies were done since the previous evaluation, record "0" in the space provided. If more biopsies were done than spaces provided, check the box at the end of the BIOPSIES section and document the additional biopsy dates in the COMMENTS section of the form packet (i.e., end of the LX section). Precede the comment with the keywords "MORE BIOP."

I.8 NUMBER OF CHOLANGIOGRAMS DONE AT THIS EVALUATION OR SINCE THE LAST EVALUATION

Document any and all cholangiograms that were done at the time of this evaluation or since the previous evaluation period.

Completing Form: Record the number of cholangiograms that were done since the previous evaluation and record the date(s) (month/day/year) of each. If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99). If no cholangiograms were done since the previous evaluation, record "0" in the space provided. If more cholangiograms were done than spaces provided, check the box at the end of the CHOLANGIOGRAMS section and document the additional cholangiogram dates in the COMMENTS section of the form packet (i.e., end of the LX section). Precede the comment with the keywords "MORE CHOL."

I.9 NUMBER OF ULTRASOUNDS DONE AT THIS EVALUATION OR SINCE THE LAST EVALUATION

Document any and all ultrasounds that were done at the time of this evaluation or since the previous evaluation period.

Completing Form: Record the number of ultrasounds that were done since the previous evaluation and record the date(s) (month/day/year) of each. If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99). If no ultrasounds were done since the previous evaluation, record "0" in the space provided. If more ultrasounds were done than spaces provided, check the box at the end of the ULTRASOUNDS section and document the additional ultrasound dates in the COMMENTS section of the form packet (i.e., end of the LX section). Precede the comment with the keywords "MORE ULTRA."

II. NUMBER OF HOSPITALIZATIONS SINCE LAST EVALUATION

Any hospitalizations that the patient may have experienced since the previous evaluation that lasted three or more days should be documented here and the subsequent information must be provided as defined. The information recorded should reflect the period of time from the date of the previous evaluation to the date of this evaluation. Only those hospitalizations that clearly lasted at least three days or terminated in death should be documented. ***If it is unclear as to how long the hospitalization was, do not record it.*** All hospitalizations are to be recorded regardless of whether the admitting hospital is an LTD clinical center.

Completing Form: Record the number of times since the previous evaluation that the patient has been hospitalized for three or more days and/or died during hospitalization and provide the additional information for each hospitalization. If the patient has not been hospitalized since the previous evaluation for three or more days, and has not died during hospitalization, record "0" in the space provided. If there are more hospitalizations than spaces provided, check the box at the end of the HOSPITALIZATIONS section and document the hospitalization and corresponding information in the COMMENTS section of the form packet (i.e., end of the LX section). Precede the comment with the keywords "MORE HOSP."

- Admission Date - Record the date (month/day/year) that the patient was admitted to the hospital. If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99). If the admission occurred during the previous evaluation period, record NA for the admission date.

- Days in ICU – Record the number of days that the patient was in an intensive care unit during the hospitalization period. If the patient was not in an intensive care unit during the hospitalization, record " 0 " in the column. If the information is unavailable, record UNK for unknown. If the ICU stay began during the previous evaluation period, or ended after the current evaluation period, enter only the number of days during this current evaluation period.

- Discharge Date – Record the date (month/day/year) that the patient was discharged from the hospital. If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99). If discharge occurred after the current evaluation period, i.e., patient is still in the hospital when form is closed, record N/A for the discharge date. ***If the patient was hospitalized and received a liver retransplant, record N/A for the discharge date of that hospitalization. Patient follow-up ceases on the date of retransplantation, therefore any information that pertains to a time after the retransplantation date is not applicable. Note: not applicable (-2) for a discharge date will be an edits error and will require an edit bypass.***

- Reason(s) for Hospitalization – More than one reason may be specified. Refer to the "Reason(s) for Hospitalization" code list below the question and place a check next to each code number that corresponds to a reason for the current hospitalization. If a reason for hospitalization is "7. Other," specify the reason for hospitalization in the space provided.

REASON(S) FOR HOSPITALIZATION

1. Follow-up evaluation
2. Recurrent disease
3. Acute Rejection
4. Chronic Rejection
5. Infection
6. Retransplantation
7. Other, specify

- Other, Specify – Document the specific reason for the hospitalization only if that reason is not already listed in the "Reason(s) for Hospitalization" code list and code "7. Other" is checked. Note: specification is limited to 30 characters.

III. MEDICATIONS GIVEN DURING THIS EVALUATION PERIOD

Document the use (during this evaluation period) of medications that are listed on the page opposite the question. The meds are separated into two categories: Immunosuppressants and Other Medications.

MEDICATIONS TO BE INCLUDED

IMMUNOSUPPRESSANTS	OTHER MEDICATIONS
Cyclosporine (Neoral, Sandimmune)	Famciclovir (Famvir)
Tacrolimus (Prograf)	Hepatitus B Immune Globulin (HBIG)
Mycophenolate Mofetil (Cellcept)	Interferon (Intron-A, Roferon)
Azathioprine (Imuran)	Lamivudine (Epivir-HBV)
Prednisone	Ribavirin (Rebetrol)
Methylprednisolone (Solumedrol)	
Basilixumab (Simulect)	
Rapamycin (Sirolimus)	
Daclizumab (Zenapax)	
OKT3	

Completing Form: Document the medication and the corresponding information within the appropriate category. For each medication given during this evaluation period, record the medication code and medication name as listed on the page opposite the question. If the medication was initiated during this evaluation period, record the date that the medication was started and record the code for the reason the medication was given. If the medication was discontinued during this evaluation period, record the date and the code for the reason the medication was terminated. If more medications were given than spaces provided, check the box at the end of the MEDICATIONS section and document the medications and corresponding information in the COMMENTS section of the form packet (i.e., end of the LX section). Precede the comment with the keywords "MORE MEDS."

- Med. Code - Refer to the "Medications to be Included" code list on the page opposite the question and record the code number that corresponds to the medication given during this evaluation period.

- Medication Name – Record the name of the medication (as listed) that was given during this evaluation period. Note: specification is limited to 30 characters.

- Initiation, Start Date – If the medication was initiated during this evaluation period, record the date (month/day/year) that the medication was started. If the medication is continuing from the previous evaluation period, record "NA" in the space provided for the Start Date. If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99).

- Initiation, Reason – If the medication was initiated during this evaluation period, refer to the "Reasons for Change of Medication" code list on the page opposite the question and record the code number that corresponds to the reason that the medication was started. If the reason for medication initiation is not provided, record code number "7. Initiated for Other Reason" and specify the reason in the next column.

- Initiation, If Other, Specify - If the reason for medication initiation is code number "6. Initiated for Treatment of Recurrent Disease" specify the original liver disease that recurred in the space provided. If the reason for medication initiation is "7. Initiated for Other Reason" specify the reason in the space provided. Note: specification is limited to 30 characters.

REASONS FOR CHANGE OF MEDICATION

CODE	REASON
1.	Initiated as routine immunosuppression
2.	Initiated as study drug
3.	Initiated for treatment of acute rejection
4.	Initiated for treatment of chronic rejection
5.	Initiated for treatment of autoimmune disease
6.	Initiated for treatment of recurrent disease (specify original liver disease)
7.	Initiated for other reason (specify)
8.	Discontinued as study drug
9.	Discontinued for weaning from immunosuppression
10.	Discontinued due to HCV infection
11.	Discontinued due to renal toxicity
12.	Discontinued due to neurotoxicity
13.	Discontinued due to other complication (specify)
14.	Discontinued due to other reason (specify)

- Termination, Stop Date – If the medication was stopped during this evaluation period record the date (month/day/year) of medication termination. If medication is continuing at the time of evaluation, record "NA" in the space provided for the Stop Date. If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99).

- Termination, Reason – If the medication was stopped during this evaluation period, refer to the "Reasons for Change of Medication" code list on the page opposite the question and record the code number that corresponds to the reason the medication was stopped. If the reason for medication termination is not provided, record code number "14. Discontinued Due to Other Reason" and specify the reason in the next column.

- Termination, If Other, Specify – If the reason for medication termination is "13. Discontinued Due to Other Complication" specify the complication that occurred in the space provided. If the reason for medication termination is "14. Discontinued Due to Other Reason" specify the reason in the space provided. Note: specification is limited to 30 characters.

IV. *GRAFT DYSFUNCTION REQUIRING DIAGNOSTIC OR THERAPEUTIC INTERVENTION SINCE LAST EVALUATION.*

Document the causes of graft dysfunction that have occurred since the previous evaluation period that required diagnostic or therapeutic intervention (i.e., biopsy, cholangiogram, or change in medication) and provide the subsequent information as defined. List each cause of graft dysfunction separately (one per line) along with the corresponding information. Repeated exacerbations of graft dysfunction for a given cause should be treated as one ongoing episode of graft dysfunction. The information recorded should reflect the period of time from the date of the previous evaluation to the date of this evaluation.

Completing Form: ***Record the number of causes of graft dysfunction that occurred since the previous evaluation period and record the additional information for each cause of graft dysfunction.*** If graft dysfunction has not occurred since the previous evaluation period, record "0" in the space provided. If there are more instances of graft dysfunction than spaces provided, document the additional graft dysfunction and corresponding information in the COMMENT section of the form packet (i.e., end of the LX section). Precede the comment with the keywords "MORE GRAFT."

- Cause – Refer to the "Underlying Cause of Dysfunction" code list below the question and record the code number that ***corresponds to the cause of the dysfunction.*** If ***the cause of graft dysfunction*** is not listed, record "19. Other" and specify the cause in the next column. If there is more than one cause of graft dysfunction, ***list each cause separately*** determine which cause is secondary and document it in the COMMENTS section of the form packet (i.e., end of the LX section).

UNDERLYING CAUSE OF DYSFUNCTION

1. Uncertain	10. Viral hepatitis A
2. Acute rejection	11. Viral hepatitis B
3. Chronic rejection	12. Viral hepatitis B & D
4. Biliary strictures/obstruction/stones (obstructive cholangiopathy)	13. Viral hepatitis C
	14. Viral hepatitis E
5. Alcohol abuse	15. Viral hepatitis unknown
6. Primary biliary cirrhosis	16. Steatosis
7. Primary sclerosing cholangitis	17. Primary non-dysfunction (within 1st …)
8. Autoimmune hepatitis	18. Liver biopsy complication, specify
9. Neoplasm, specify	19. Other, specify

- If Neoplasm, Biopsy Complic., or Other, Specify – If the cause of graft dysfunction is "9. Neoplasm," "18. Liver Biopsy Complication," or "19. Other" specify the type of neoplasm, biopsy complication, or other cause of graft dysfunction in the space provided. Note: specification is limited to 30 characters.

- Cont. from Prev. Eval. - Place a check in this column if graft dysfunction was present and unresolved at the end of the previous evaluation period and is continuing into this evaluation period.

- Onset Date – If the episode of graft dysfunction began during this evaluation period, record the date of onset (month/day/year). If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99).

- How was dysfunction determined? – Determination of how graft dysfunction is confirmed must be made by the LTD PI at your center. Document all of the methods used in determining the graft dysfunction: biochemical, histological, serological, radiological, clinical, and/or toxicological. Place a check in the appropriate column if the method was employed and confirmed graft dysfunction. Leave the column blank if the method was employed but did not confirm graft dysfunction. Record "ND" in the column if the methodological tests were not done. ***If an episode of graft dysfunction is continuing from the previous evaluation period, document only those methods employed during this current evaluation period to determine dysfunction.***

- Recur. Disease – Place a check in this column if recurrence of the original liver disease contributed to graft dysfunction.

- Outcome/Current Status – Refer to the "Outcome/Current Status Code" list below the question and record the code number that corresponds to the outcome or current status of the graft dysfunction at the time of this evaluation.

  At the time of this evaluation, if the patient is not symptomatic or suffering an exacerbation of graft dysfunction, record "1" (resolved/controlled) for the outcome/current status and record the date on which the LAST episode was resolved/controlled.

  At the time of this evaluation, if the patient is symptomatic or suffering an exacerbation of graft dysfunction, record "2" (unresolved…) for the outcome/current status.

  1 = Resolved/Controlled
  Graft dysfunction was treated and is completely resolved or is controlled at the time of this evaluation.

  2 = Unresolved/Continuing/Worsening
  Graft dysfunction is unresolved, continuing and/or worsening. In this case, the dysfunction must be documented as a "continuing episode from last evaluation" at the next evaluation timepoint.

  3 = Retransplantation
  Patient received retransplantation while experiencing the noted graft dysfunction and the dysfunction contributed to the patient's need for retransplantation.

  4 = Died
  Patient died while experiencing the noted graft dysfunction and the dysfunction contributed to death.

  5 = Cannot Determine
  All sources of patient information have been exhausted and the outcome/current status remains unknown.

- If Resolved, ReLT, or Died Date – ***At the time of this evaluation, if graft dysfunction is not present (i.e., is resolved/controlled)*** or the patient received retransplantation or died, record the date (month/day/year) of the applicable event. If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99). ***Note: date of resolution is the date on which the LAST episode of graft dysfunction was resolved.***

V. ANY NEOPLASIA PRESENT DURING THIS EVALUATION PERIOD?

Any neoplasia that were present during this evaluation period should be documented here and the subsequent information must be provided as defined. The information recorded should reflect the period of time from the date of the previous evaluation to the date of this evaluation. For neoplasms that occurred more than once, list each occurrence separately (one per line). For PTLD/Lymphomas, list each treatment and the corresponding information separately (one per line).

Completing Form: Check "Yes" if any neoplasms were present during this evaluation period and record the additional information. Check "No" if there is no evidence of neoplasia since the previous evaluation period. If there are more instances of neoplasia and/or treatments than spaces provided, check the box at the end of the NEOPLASIA section and document the additional neoplasms, treatments, and corresponding information in the COMMENTS section of the form packet (i.e., end of the LX section). Precede the comment with the keywords "MORE NEO."

- Site Code – Refer to the "Neoplasia Site Codes" list on the page opposite the question and record the code number that corresponds to the site of the neoplasm. If the site is not listed, record code "26. Other" and specify the site in the third column.

NEOPLASIA SITE CODES

1. Bladder	10. Oral	19. PTLD/Lymphoma
2. Bone	11. Ovary	20. Skin - arms
3. Brain/CNS	12. Pancreas	21. Skin - upper back
4. Breast	13. Prostate	22. Skin - chest
5. Colon/Rectum	14. Stomach	23. Skin - face/neck/scalp
6. Esophagus	15. Uterus	24. Skin - legs
7. Kidney	16. Cervical dysplasia	25. Skin - trunk
8. Liver	17. Systemic - leukemia	26. Other (specify)
9. Lung	18. Systemic - multiple myeloma	

- Type Code – To be recorded for skin cancer and PTLD/Lymphomas only. Refer to the "Neoplasia Type Codes" list on the page opposite the question and record the code number that corresponds to the type of skin cancer or PTLD/Lymphoma that is evident. If the type is not listed, record code "7. Other " and specify the type in the next column.

NEOPLASIA TYPE CODES

(for PTLD/Lymphoma only)
1. EBV
2. Hodgkin's, non-EBV
3. Non-Hodgkin's, non-EBV

(for skin cancer only)
4. Basal Cell
5. Squamous Cell
6. Melanoma
7. Other (specify)

- If Other, Specify – If the neoplasm Site Code is "26. Other" and/or the neoplasm Type Code is "7. Other," specify the site and/or the type in the space provided.

- Cont. from Prev. Eval. – Place a check in this column if the neoplasm was present and unresolved at the end of the previous evaluation period and is continuing into this evaluation period. The neoplasm cited must have been documented on a previous follow-up evaluation.

- If New, Date of Diagnosis – Date of first onset during this evaluation period. Record the date (month/day/year) that the neoplasm was first diagnosed. The date recorded should be within the period of time between the previous evaluation and this current evaluation.

- Primary/Metast. – Document whether the neoplasm is primary or metastatic. Circle "P" if the neoplasm is in the primary or originating site. Circle "M" if the neoplasm is a metastatic or secondary growth in a new location arising from a different primary site.

- Treatment Code – To be recorded for PTLD/Lymphomas only. Refer to the "Treatment Codes for PTLD/Lymphoma Only" list on the page opposite the question and record on separate lines the code numbers that correspond to each type of treatment that was administered (for multiple treatment lines, use dittos (") to indicate repeated information in preceding rows). If no treatment was administered, record " 0 " (for none) in the column. If the treatment administered is not listed, call the Data Coordinating Center for a new code number.

TREATMENT CODES FOR PTLD/LYMPHOMA ONLY

0. None
1. Decreased/stopped immunosuppressive meds
2. Resection
3. Radiation
4. Chemotherapy
5. Hormone

- Treatment Start Date – To be recorded for PTLD/Lymphomas only. Record the date (month/day/year) that each PTLD/Lymphoma treatment began. If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99). If treatment began before the evaluation period, record a NA for the start date.

- Treatment Stop Date – To be recorded for PTLD/Lymphomas only. Record the date (month/day/year) that each PTLD/Lymphoma treatment was terminated. If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99). If treatment has not ended and is continuing into the next evaluation period, record NA for the stop date.

VI. ANY RECURRENCE OF DISEASE SINCE LAST EVALUATION?

Document any recurrence of the original liver disease (as diagnosed pre-transplant) since the previous evaluation. The information recorded should reflect the period of time from the date of the previous evaluation to the date of this evaluation. Refer to the "Definitions for Recurrent Disease" list on the page opposite the questions. For any given disease ALL criteria must be met.

Completing Form: Check "Yes" if diagnosis of the original liver disease recurrence has been made since the previous evaluation. If "Yes," place a check next to all the liver diseases that have recurred during this evaluation period and provide the additional information as defined. Check "No" if there has been no recurrence of the original liver disease since the previous evaluation.

VI.1 PRIMARY BILIARY CIRRHOSIS (PBC)

PBC Criteria: Pre-transplant diagnosis of PBC including AMA positive. ***Post-transplant characteristics showing*** histopathologic changes on biopsy including "florid" duct lesions or non-suppurative cholangitis, and an absence of adverse drug reaction, biliary tract obstruction or stricturing or deep fungal or mycobacterial infection that would produce similar histopathologic changes.

Completing Form: Check if patient was diagnosed with primary biliary cirrhosis pre-transplant and diagnosis of recurrent PBC has been made since the previous evaluation. Record the date of onset (month/day/year) of the recurrence. The date recorded should be within the period of time between the previous evaluation and this current evaluation. If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99).

VI.2 PRIMARY SCLEROSING CHOLANGITIS (PSC)

PSC Criteria: Pre-transplant diagnosis of PSC. ***Post-transplant*** cholangiographic evidence of intrahepatic biliary tract obstruction or stricturing typical of PSC, without an apparent cause, and histopathologic changes typical of PSC that are not consistent with either acute or chronic rejection, or other well recognized patterns of non- PSC-related liver disease in recipients where other causes of biliary strictures have been reasonably excluded.

Completing Form: Check if the patient was diagnosed with primary sclerosing cholangitis pre-transplant and diagnosis of recurrent PSC has been made since the previous evaluation. Record the date of onset (month/day/year) of the recurrence. The date recorded should be within the period of time between the previous evaluation and this current evaluation. If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99).

VI.3 AUTOIMMUNE HEPATITIS (AIH)

Autoimmune Hepatitis Criteria: Pre-transplant diagnosis of AIH including an ANA titer ≥ 1:80; presence of an LKM or ASMA at a similar titer. Rule out HCV and all other causes. Increased gammaglobulin level > 2 times the upper limits of normal (per Dr. Czaja). Post-transplant ANA, ASMA, or LKM antibody positive with titer > 1:80, negative HCV-RNA by PCR, and negative HBsAg in serum, ***with biochemical evidence or*** histopathologic changes typical of chronic hepatitis, but not consistent with either acute or chronic rejection or other well recognized patterns of non-chronic hepatitis-related liver injury.

Completing Form: Check if patient was diagnosed with autoimmune hepatitis pre-transplant and diagnosis of recurrent AIH has been made since the previous evaluation. Record the date of onset (month/day/year) of the recurrence. The date recorded should be within the period of time between the previous evaluation and this current evaluation. If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99).

VI.4 NEOPLASM

Neoplasm Criteria: Pre-transplant diagnosis of neoplasm. ***Post-transplant*** histopathologic evidence of a neoplastic disorder.

Completing Form: Check if patient was diagnosed with a neoplasm pre-transplant and diagnosis of the same neoplasm has been made since the previous evaluation. Record the date of onset (month/day/year) of the recurrence. The date recorded should be within the period of time between the previous evaluation and this current evaluation. If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99). NOTE: any neoplasm documented here should also be documented in section V. NEOPLASIA.

VI.4.1 TYPE

If a recurrent neoplasm was diagnosed, specify the type in the space provided. Note: type specification is limited to 30 characters.

VI.4.2 SITE

If a recurrent neoplasm was diagnosed, check whether it is intrahepatic or extrahepatic. If both intra- and extrahepatic tissue are involved, check both intrahepatic and extrahepatic.

VI.5 HEPATITIS

Refer to the "Definitions for Recurrent Disease" on the page opposite the questions for definitions of hepatitis A, B, B+D, C, and Unknown. Record only the recurrence of the specific type of hepatitis that was diagnosed pre-transplant. Do not record any new diagnoses of hepatitis A, B, B+D, C, Unknown, or Other.

Completing Form: Check if diagnosis of recurring hepatitis has been made and check the type(s) of hepatitis that were diagnosed. If a type of hepatitis was diagnosed as recurring and is not listed, check "5.7 Other" and specify the type in the space provided. Record the date of onset (month/day/year) of hepatitis recurrence. ***If patient is diagnosed with more than one type of recurrent hepatitis with different onset dates, check all types of hepatitis that recurred and record the earliest onset date.*** The date recorded should be within the period of time between the previous evaluation and the current evaluation. If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99). Note: type specification is limited to 30 characters.

VI.5.1 HEPATITIS VIRAL A (HAV)

Hepatitis A Criteria: Pre-transplant diagnosis of hepatitis A and anti-HAV IgM and/or IgG positive ***pre-transplant***. Post-transplant anti-HAV IgM and/or IgG positive ***with presence of biochemical*** or histopathologic evidence.

Completing Form: Check if patient was diagnosed with hepatitis A pre-transplant and diagnosis of recurrent hepatitis A has been made since the previous evaluation.

VI.5.2 HEPATITIS VIRAL B (HBV)

Hepatitis B Criteria: Pre-transplant diagnosis of hepatitis B and HBsAg positive ***pre-transplant***. Post-transplant HBsAg positive ***or*** HBV-DNA positive ***with presence of biochemical or histologic evidence.***

Completing Form: Check if patient was diagnosed with hepatitis B pre-transplant and diagnosis of recurrent hepatitis B has been made since the previous evaluation.

VI.5.3 HEPATITIS VIRAL B & DELTA

Hepatitis B & Delta Criteria: Pre-transplant diagnosis of hepatitis B and Delta, and HBsAg positive and ***anti-HDV IgM positive pre-transplant. HDV antigen positive post-transplant , and meet criteria for recurrent HBV.***

Completing Form: Check if patient was diagnosed with hepatitis B & Delta pre-transplant and diagnosis of recurrent hepatitis B & Delta has been made since the previous evaluation.

VI.5.4 HEPATITIS VIRAL C (HCV)

Hepatitis C Criteria: Pre-transplant diagnosis of hepatitis C and anti-HCV positive or HCV-RNA positive by PCR ***pre-transplant.*** Post-transplant HCV-RNA positive by PCR, ***and evidence of graft dysfunction with presence of biochemical and histologic evidence post-transplant.***

Completing Form: Check if patient was diagnosed with hepatitis C pre-transplant and diagnosis of recurrent hepatitis C has been made since the previous evaluation.

VI.5.5 HEPATITIS UNKNOWN (CRYPTOGENIC)

Hepatitis Unknown Criteria: Pre-transplant diagnosis of hepatitis unknown. ***Presence of biochemical or*** histologic evidence of hepatitis post-transplant with no evidence of known viral hepatitis pathogens such as HAV, HBV, HCV, EBV, etc.

Completing Form: Check if patient was diagnosed with hepatitis unknown (cryptogenic) pre-transplant and diagnosis of recurrent hepatitis unknown has been made since the previous evaluation.

VI.5.6 NON-ALCOHOLIC STEATO-HEPATITIS (NASH)

NASH Criteria: Pre-transplant evidence of fatty metamorphosis with or without Mallory's hyaline and parenchymal PMN infiltrates and necrosis on liver biopsy. ***No diagnosis of ALD pre-transplant.*** Fatty metamorphosis with or without Mallory's hyaline and parenchymal PMN infiltrates and necrosis on liver biopsy ***post-transplant with*** no evidence of alcohol use. Exclude patient with J-I bypass or prolonged TPN.

Completing Form: Check if patient was diagnosed with non-alcoholic steato-hepatitis pre-transplant and diagnosis of recurrent NASH has been made since the previous evaluation.

VI.5.7 OTHER

Diagnosis of a type of hepatitis pre-transplant that is not already listed in section VI.5 and diagnosis of that same hepatitis since the previous evaluation period.

Completing Form: Check if patient was diagnosed with an "Other" type of hepatitis pre-transplant and diagnosis of that same "Other" hepatitis recurrence has been made since the previous evaluation.

VI.6 ALCOHOLIC LIVER DISEASE (ALD)

ALD Criteria: Pre-transplant diagnosis of ALD. Fatty metamorphosis with or without Mallory's hyaline and parenchymal PMN infiltrates and necrosis on liver biopsy in a patient who has returned to drinking; exclude patients with diabetes, J-I bypass, or prolonged TPN. Admission of recidivism, and other objective evidence of significant alcohol intake (i.e., blood alcohol levels, desialylated transferrin levels) ***post-transplant***.

Completing Form: Check if patient was diagnosed with alcoholic liver disease pre-transplant and diagnosis of recurrent ALD has been made since the previous evaluation. Record the date of onset (month/day/year) of the recurrence. The date recorded should be within the period of time between the previous evaluation and the current evaluation. If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99).

VI.7 HEMOCHROMATOSIS

Hemochromatosis Criteria: Pre-transplant diagnosis of hemochromatosis (presence of gene, or hepatic iron index > 1.9). Post-transplant increased iron staining > "mild" on liver biopsy.

Completing Form: Check if patient was diagnosed with hemochromatosis pre-transplant and diagnosis of recurrent hemochromatosis has been made since the previous evaluation. Record the date of onset (month/day/year) of the recurrence. The date recorded should be within the period of time between the previous evaluation and the current evaluation. If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99).

VI.8 OTHER, CODE LIVER DISEASE DIAGNOSIS

Document diagnosis made since the previous evaluation of any pre-transplant liver disease that is not already listed in section VI. Refer to the "Liver Disease Diagnoses" code list on the back of the question page.

LIVER DISEASE DIAGNOSES

1. Acute hepatitis A
2. Acute hepatitis B
3. Acute hepatitis B and D
4. Acute hepatitis C
5. Acute hepatitis other (specify: e.g., drug or toxin, presumed viral, CMV, EBV, etc.)
6. Acute hepatitis of unknown cause
7. Alcoholic liver disease (Laennec's cirrhosis)
8. Alpha-1-antitrypsin deficiency
9. Benign tumor (specify: e.g., adenoma)
10. Biliary atresia
11. Budd-Chiari syndrome
12. Chronic cholestatic syndrome of childhood (specify: e.g., Bylers, Alagilles, nonsyndromatic paucity of bile duct, etc.)
13. Chronic autoimmune (lupoid) hepatitis/cirrhosis
14. Chronic hepatitis B/cirrhosis
15. Chronic hepatitis B and D/cirrhosis
16. Chronic hepatitis C/cirrhosis
17. Chronic hepatitis/cirrhosis other (specify: e.g., drug or toxin, presumed viral, etc.)
18. Chronic hepatitis/cirrhosis of unknown cause
19. Congenital biliary and fibrocystic disease (specify: e.g., congenital hepatic fibrosis, Caroli's disease, etc.)
20. Glycogen storage disease (specify type)
21. Hemochromatosis
22. Homozygous hypercholesterolemia
23. Hyperalimentation-induced liver disease
24. Malignancy, cholangiocarcinoma
25. Malignancy, fibrolamellar hepatocellular carcinoma
26. Malignancy, hepatocellular carcinoma
27. Malignancy, other (specify: e.g., angiosarcoma, hemangioendothelioma, hepatoblastoma, etc.)
28. Metastatic malignancy (specify: e.g., carcinoma of breast, colon, lung, etc.)
29. Neonatal or pediatric post-hepatic cirrhosis
30. Primary biliary cirrhosis
31. Primary sclerosing cholangitis
32. biliary cirrhosis (specify cause: e.g., gall stones, stricture, etc.)
33. Tyrosinemia
34. Wilson's disease
35. Other (specify: e.g., trauma, cystic fibrosis, etc.)

Completing Form: Check if patient was diagnosed pre-transplant with a liver disease other than those already listed, and diagnosis of that same recurrent liver disease has been made since the previous evaluation. Record the date of onset (month/day/year) of the recurrence. The date recorded should be within the period of time between the previous evaluation and the current evaluation. If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99). Refer to the "Liver Disease Diagnoses" code list on the back of the question page, and record the corresponding liver disease diagnosis code and specify as required (code 5, 9, 12, 17, 19, 20, 27, 28, 32, and 35) in the spaces provided. Note: specification is limited to 30 characters.

VII. ANY MAJOR EVENTS/CONDITIONS SINCE LAST EVALUATION?

Document instances of specific major events or conditions that the patient may have experienced during the current evaluation period, whether continuing from the previous evaluation, or occurring as a new event/condition, or as a new episode of a previously resolved event/condition. For each occurrence of a major event/condition the subsequent information must be provided as defined. Regardless of the number of times an event/condition occurs within an evaluation period, only the first episode ***or first exacerbation*** of the event/condition is to be recorded for that period unless otherwise stated. A definition for each event/condition is provided. However, in the absence of these criteria, a clear diagnosis in the patient chart of the event/condition may be used, unless otherwise noted for the specific event/condition.

Completing Form: Check "Yes" if the patient has experienced any major event/condition ***or exacerbation*** since the previous evaluation and document the subsequent information as defined for each event/condition. Major event/condition categories include Cardiovascular, Diabetes Mellitus, Renal Insufficiency, Abdominal, Biliary, Neurologic, Psychiatric, and Metabolic, Toxic, Other. Check "No" if the patient has not experienced any major event or condition since the previous evaluation.

Place a check next to each major event/condition that occurred during this evaluation period and was specified in the patient's chart or other records. Events/conditions that were not present or were not significant enough in the patient's clinical condition to warrant a note in the chart, leave blank. No special "unknown" or "not specified" codes will be used.

GENERAL INSTRUCTIONS

- Cont. from Prev. Eval. – Place a check in this column if the major event/condition was present and unresolved at the end of the previous evaluation period and is continuing into this evaluation period. The major event/condition cited must have been documented on the previous follow-up evaluation.
  EXCEPTION: for the initial follow-up evaluation, any major event/condition that is continuing at the beginning of the hiatus (07/01/95) should be coded as a continuation, regardless of whether it was one of the complications collected on the MF form during the LTD operational phase.

- If New, Date of Onset – If the major event/condition is not continuing from the previous evaluation period, record the date of first onset (i.e., the date of diagnosis; month/day/year) during this evaluation period. The date recorded should be within the period of time between the previous evaluation and this current evaluation. For example, if the patient experienced several GI bleeds since the previous evaluation, record the onset (diagnosis) date of the earliest bleed during this evaluation period. If an event/condition was resolved during the last evaluation period and has since recurred as a new episode, record the onset date of this new episode and the current status. If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99).

- Outcome/Current Status – Refer to the "Outcome/Current Status Code" list on the page opposite the question and record the code number that corresponds to the outcome of the major event/condition at the time of this evaluation.

  At the time of this evaluation, if the patient is not symptomatic or suffering an exacerbation of a major event/condition, record "1" (resolved/controlled) for the outcome/current status and record the date on which the LAST episode was resolved/controlled.

  At the time of this evaluation, if the patient is symptomatic or suffering an exacerbation of a major event/condition, record "2" (unresolved…) for the outcome/current status.

  1 = Resolved/Controlled
  The major event/condition is completely resolved at the time of this evaluation (such as a pneumothorax), or is controlled (such as hypertension or atrial arrhythmia).

  2 = Unresolved/Continuing/Worsening
  The major event/condition is unresolved, continuing and/or worsening at the time of this evaluation.

  3 = Retransplantation
  The patient received a retransplant while experiencing the noted event/condition ***and the event/condition contributed to the patient's need for a liver retransplant.***

  4 = Died
  The patient died while experiencing the noted event/condition ***and the event/condition contributed to the patient's death.***

  5 = Cannot Determine
  All sources of patient information have been exhausted and the outcome/current status remains unknown.

- If Resolved, Date of Resolution – If the major event/condition was resolved/controlled, record the date (month/day/year) of resolution. If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99). ***Note: date of resolution is the date on which the LAST episode of the major event/condition was resolved.***

VII.1 CARDIOVASCULAR

VII.1.1 HYPERTENSION (TREATED)

Sustained blood pressure > 150/95 that requires medical treatment such as drug and/or diet therapy. This includes elevated blood pressure due to renal, endocrine, mechanical, or toxic (e.g., toxemia) diseases as well as those cases of unknown causes.

Completing Form: Check if hypertension occurred and complete the remaining columns as instructed in the General Instructions for this section (VII).

VII.1.2 CARDIOMYOPATHY

Inability of the heart to adequately pump blood, accompanied (in some instances) by disturbed heart rhythm that leads to arrhythmias. Confirmation of heart enlargement via diagnostic tests such as chest x-ray, echocardiogram, radionuclide ventriculogram, or cardiac catheterization. An electrocardiogram will reveal any abnormal electrical activity of the heart.

Completing Form: Check if cardiomyopathy occurred and complete the remaining columns as instructed in the General Instructions for this section (VII).

VII.1.3 PULMONARY HYPERTENSION

Pulmonary arterial blood pressure that is > 25 mm Hg at rest or > 30 mm Hg during exercise, confirmed by echocardiographic examination.

Completing Form: Check if pulmonary hypertension occurred and complete the remaining columns as instructed in the General Instructions for this section (VII).

VII.1.4 VENTRICULAR ARRHYTHMIA

Any deviation from normal sinus rhythm that originates in the ventricles. The arrhythmia should be prolonged and/or treated to be classified as a major event. Examples of ventricular arrhythmias include frequent PVC's and ventricular tachycardia not associated with cardiopulmonary arrest.

Completing Form: Check if ventricular arrhythmia occurred and complete the remaining columns as instructed in the General Instructions for this section (VII).

VII.1.5 CONGESTIVE HEART FAILURE (CHF)

Inability of the heart to maintain adequate blood flow. Results in congestion of blood in certain veins and organs with an inadequate supply of blood to body tissues. Pulmonary and lower extremity edema may occur.

Completing Form: Check if congestive heart failure occurred and complete the remaining columns as instructed in the General Instructions for this section (VII).

VII.1.6 ANGINA

Episodes of steady pain and feeling of pressure about the heart characterized by pain radiating from the chest to the shoulder and possibly down the left arm. Caused by poor blood supply to the heart.

Completing Form: Check if angina occurred and complete the remaining columns as instructed in the General Instructions for this section (VII).

VII.1.7 MYOCARDIAL INFARCTION (MI)

Interruption of blood supply to an area of the myocardium resulting in necrosis. Diagnosis is made by EKG with positive CPK and MB bands. In the case that an EKG reveals a probable silent MI in the past, check here and record UNK under "If New, Date of Onset."

Completing Form: Check if myocardial infarction occurred and complete the remaining columns as instructed in the General Instructions for this section (VII).

VII.1.8 CARDIOPULMONARY ARREST

Sudden cessation of cardiac activity associated with a lack of respiration. Document only complete cardiopulmonary arrests requiring CPR. Do not check if the patient suffered only respiratory arrest that was not accompanied by ventricular fibrillation or ventricular standstill.

Completing Form: Check if cardiopulmonary arrest occurred and complete the remaining columns as instructed in the General Instructions for this section (VII).

VII.1.9 OTHER CARDIOVASCULAR EVENTS, SPECIFY

Document any other diagnosed cardiovascular events that are not already listed in the cardiovascular section VII.1.

Completing Form: Check if other cardiovascular events occurred and complete the remaining columns as instructed in the General Instructions for this section (VII).

VII.1.10 CORONARY INTERVENTION

Document any catheter based intervention or surgical procedure intended to improve an existing coronary condition.

CODES

1. Coronary angioplasty
2. MIDCAB (Minimally Invasive Direct Coronary Artery Bypass)
3. CABG (Coronary Artery Bypass Graft surgery)
4. Laser myocardial revascularization
5. Angiogenesis
6. Other, specify

Completing Form: Check if coronary intervention was administered since the previous evaluation. Record the date (month/day/year) on which each intervention was administered. The date recorded should be within the period of time between the previous evaluation and this current evaluation. If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99). Refer to the "Codes" list below the question and record the code number that corresponds to the type of intervention. If the type of intervention is not listed, record code "6. Other" and specify the type in the space provided. Note: type specification is limited to 30 characters. If more interventions were administered than spaces provided, check the box at the end of the CORONARY INTERVENTION section and document the additional interventions and corresponding information in the COMMENTS section of the form packet (i.e., end of the LX section). Precede the comment with the keywords "MORE CARD."

VII.2 DIABETES MELLITUS (IF TREATED)

Document any diabetes mellitus (types I or II) requiring prolonged treatment such as diet therapy, oral hypoglycemic drugs and/or insulin to maintain a serum glucose level within acceptable limits. Do not include occasional insulin coverage that may be needed during an immediate post-operative period or during a steroid bolus.

VII.2.1 DIET CONTROLLED

Presence of diabetes mellitus with a fasting blood sugar > 130 mg/dl which is controlled by diet therapy and does not require medication or insulin to maintain a serum glucose within acceptable limits.

Completing Form: Check if diabetes mellitus occurred and was controlled by diet therapy. Complete the remaining columns as instructed in the General Instructions for this section (VII).

VII.2.2 ORAL MEDICATION

Presence of diabetes mellitus with a fasting blood sugar > 130 mg/dl which is controlled by oral hypoglycemic medication and does not require insulin to maintain a serum glucose within acceptable limits. In this population, adult-onset diabetes is controlled by oral hypoglycemic medication.

Completing Form: Check if diabetes mellitus occurred and was controlled by oral medications. Complete the remaining columns as instructed in the General Instructions for this section (VII).

VII.2.3 USING INSULIN

Presence of diabetes mellitus with fasting blood sugar > 130 mg/dl which requires insulin to maintain a serum glucose within acceptable limits.

Completing Form: Check if diabetes mellitus occurred and was controlled by insulin. Complete the remaining columns as instructed in the General Instructions for this section (VII).

VII.3 RENAL INSUFFICIENCY (CREATININE > 2.0 mg/dl)

VII.3.1 NOT REQUIRING DIALYSIS

Sustained creatinine > 2.0 mg/dl that did not require dialysis intervention.

Completing Form: Check if renal insufficiency occurred but did not require dialysis intervention and complete the remaining columns as instructed in the General Instructions for this section (VII).

VII.3.2 REQUIRING DIALYSIS

Sustained creatinine > 2.0 mg/dl that required dialysis intervention. Dialysis is the process of removing urea and other elements from the body when a person suffers from renal insufficiency. Include both hemodialysis and peritoneal dialysis.

Completing Form: Check if renal insufficiency requiring dialysis intervention occurred and complete the remaining columns as instructed in the General Instructions for this section (VII).

VII.4 ABDOMINAL

VII.4.1 ASCITES

Free serous fluid accumulation in the peritoneal cavity. A common sign of end stage liver disease and a result of portal hypertension. The presence of ascites should be noted by the physician at the time of a physical exam.

Completing Form: Check if ascites occurred and complete the remaining columns as instructed in the General Instructions for this section (VII).

VII.4.2 VARICES, NON-BLEEDING

Presence of dilated veins in the walls of the esophagus, stomach, and small intestines.

Completing Form: Check if non-bleeding varices occurred and complete the remaining columns as instructed in the General Instructions for this section (VII).

VII.4.3 UPPER GI BLEED, VARICEAL

Presence of blood or evidence of old blood in the upper GI tract (endoscopy), gastric aspirate, and/or vomit. Bleeding from varices within the esophagus and/or stomach.

Completing Form: Check if variceal upper GI bleeding occurred and complete the remaining columns as instructed in the General Instructions for this section (VII).

VII.4.4 UPPER GI BLEED, NON-VARICEAL

Presence of blood or evidence of old blood in the upper GI tract, gastric aspirate, and/or vomit. Bleeding within the esophagus, stomach, or duodenum from an ulcer, gastritis, colitis, or Mallory Weiss tear, but not from varices.

Completing Form: Check if non-variceal upper GI bleeding occurred and complete the remaining columns as instructed in the General Instructions for this section (VII).

VII.4.5 LOWER GI BLEED

Presence of blood or evidence of old blood in the lower GI tract and/or stool (guaiac test and/or endoscopy). Bleeding within the small intestine distal to the duodenum, colon or rectum. The presence of tarry stools alone (without a guaiac test) may only be a result of the patient taking an iron supplement, which is very common, and should not be considered GI bleeding. However, stool bleeding should be included.

Completing Form: Check if lower GI bleeding occurred and complete the remaining columns as instructed in the General Instructions for this section (VII).

VII.4.6 GI BLEED, UNKNOWN

Bleeding within the esophagus, stomach, duodenum, small intestines, colon or rectum that is of an unknown cause or origin. Presence of blood or evidence of old blood in the GI tract, gastric aspirate, vomit, and/or stool (guaiac test).

Completing Form: Check if GI bleeding of an unknown origin occurred and complete the remaining columns as instructed in the General Instructions for this section (VII).

VII.4.7 VASCULAR THROMBOSIS – HEPATIC ARTERY

Presence of a blood clot or thrombus in the hepatic artery confirmed by diagnostic testing or surgical exploration.

Completing Form: Check if hepatic artery thrombosis occurred and complete the remaining columns as instructed in the General Instructions for this section (VII).

VII.4.8 VASCULAR THROMBOSIS – PORTAL VEIN

Presence of a blood clot or thrombus in the portal vein confirmed by diagnostic testing or surgical exploration.

Completing Form: Check if portal vein thrombosis occurred and complete the remaining columns as instructed in the General Instructions for this section (VII).

VII.4.9 PORTAL HYPERTENSION

Increased pressure in the portal vein that results from obstruction of blood flow, confirmed by diagnostic testing or surgical exploration.

Completing Form: Check if portal hypertension occurred and complete the remaining columns as instructed in the General Instructions for this section (VII).

VII.4.10 PORTAL VEIN PARTIAL OCCLUSION

Partial closure of the portal vein, either acquired or congenital, confirmed by diagnostic testing or surgical exploration.

Completing Form: Check if partial occlusion of the portal vein occurred and complete the remaining columns as instructed in the General Instructions for this section (VII).

VII.4.11 HEPATOPULMONARY SYNDROME

Document occurrence of hepatopulmonary syndrome as diagnosed by a physician at the clinical center or by a physician caring for the patient.

Completing Form: Check if hepatopulmonary syndrome occurred and complete the remaining columns as instructed in the General Instructions for this section (VII).

VII.4.12 CHRONIC ULCERATIVE COLITIS (CUC)

Chronic ulceration of the colon and rectum mucosa that may result in hemorrhage and perforation.

Completing Form: Check if ulcerative colitis occurred and complete the remaining columns as instructed in the General Instructions for this section (VII).

VII.4.13 CROHN'S DISEASE

Inflammation of the mucosal and submucosal membranes of the small intestines. Includes nonspecific inflammatory granulomatous lesions involving the terminal ileum.

Completing Form: Check if Crohn's disease occurred and complete the remaining columns as instructed in the General Instructions for this section (VII).

VII.5 BILIARY

VII.5.1 CHOLANGITIS (BACTERIAL WITH FEVER)

Bacterial infection of the biliary tract accompanied by fever. Diagnosis is made by liver biopsy, endoscopic retrograde cholangiopancreatography (ERCP) or percutaneous transhepatic cholangiography, or positive culture. Do not include those cases of unconfirmed cholangitis even if during the suspected episode the patient was symptomatic and treated with antibiotics.

Completing Form: Check if bacterial cholangitis occurred and complete the remaining columns as instructed in the General Instructions for this section (VII).

Note: the general instruction statement at the beginning of section VII "… in the absence of these criteria, a clear diagnosis in the patient chart … may be used" does not apply. These criteria must be met for diagnosis.

VII.5.2 ISCHEMIC CHOLANGITIS

Local and temporary anemia and inflammation of the biliary tract due to obstruction of blood flow to the tract. Obstruction or occlusion of the biliary tract should be confirmed by diagnostic testing or surgical exploration.

Completing Form: Check if ischemic cholangitis occurred and complete the remaining columns as instructed in the General Instructions for this section (VII).

Note: the general instruction statement at the beginning of section VII "… in the absence of these criteria, a clear diagnosis in the patient chart … may be used" does not apply. These criteria must be met for diagnosis.

VII.5.3 CHOLEDOCHO-CHOLEDOCHO (C-C) LEAK

Any biliary leak from a choledochocholedochostomy. Diagnosis is made by contrast radiography or surgical exploration. This type of leak may result in bile peritonitis.

Completing Form: Check if choledochocholedochostomy leak occurred and complete the remaining columns as instructed in the General Instructions for this section (VII).

Note: the general instruction statement at the beginning of section VII "… in the absence of these criteria, a clear diagnosis in the patient chart … may be used" does not apply. These criteria must be met for diagnosis.

VII.5.4 CHOLEDOCHO-JEJUNO (C-J) LEAK

Any biliary leak from a choledochojejunostomy. Diagnosis is made by contrast radiography or surgical exploration. This type of leak may result in bile peritonitis.

Completing Form: Check if choledochojejunostomy leak occurred and complete the remaining columns as instructed in the General Instructions for this section (VII).

Note: the general instruction statement at the beginning of section VII "… in the absence of these criteria, a clear diagnosis in the patient chart … may be used" does not apply. These criteria must be met for diagnosis.

VII.5.5 T-TUBE TRACT LEAK / BILIARY TUBE LEAK

Any bile leak along the T-tube or biliary tube usually confirmed by cholangiogram. This may occur after T-tube removal.

Completing Form: Check if a T-tube tract or biliary tube leak occurred and complete the remaining columns as instructed in the General Instructions for this section (VII).

Note: the general instruction statement at the beginning of section VII "… in the absence of these criteria, a clear diagnosis in the patient chart … may be used" does not apply. These criteria must be met for diagnosis.

VII.5.6 ANASTOMOTIC STRICTURES

These are choledocho-choledocho (C-C) or choledocho-jejuno (C-J) strictures. Diagnosis is made by endoscopic retrograde cholangiopancreatography (ERCP) or percutaneous transhepatic cholangiography.

Completing Form: Check if anastomotic strictures occurred and complete the remaining columns as instructed in the General Instructions for this section (VII).

Note: the general instruction statement at the beginning of section VII "… in the absence of these criteria, a clear diagnosis in the patient chart … may be used" does not apply. These criteria must be met for diagnosis.

VII.5.7 INTRA-HEPATIC STRICTURES

Abnormal narrowing of the biliary and hepatic ducts. Diagnosis is made by endoscopic retrograde cholangiopancreatography (ERCP) or percutaneous transhepatic cholangiography.

Completing Form: Check if intrahepatic strictures occurred and complete the remaining columns as instructed in the General Instructions for this section (VII).

Note: the general instruction statement at the beginning of section VII "… in the absence of these criteria, a clear diagnosis in the patient chart … may be used" does not apply. These criteria must be met for diagnosis.

VII.5.8 STRICTURES / OBSTRUCTION, NOS

Presence of stricture or obstruction that is not otherwise specified (NOS). Diagnosis is made by endoscopic retrograde cholangiopancreatography (ERCP) or percutaneous transhepatic cholangiography.

Completing Form: Check if non-specified stricture or obstruction occurred and complete the remaining columns as instructed in the General Instructions for this section (VII).

Note: the general instruction statement at the beginning of section VII "… in the absence of these criteria, a clear diagnosis in the patient chart … may be used" does not apply. These criteria must be met for diagnosis.

VII.5.9 STONES / DEBRIS

Any stones or debris in the biliary system confirmed by diagnostic testing such as a cholangiogram. The patient may or may not be symptomatic. If this condition is not treated document it here with a status code of "1. Resolved/Controlled."

Completing Form: Check if biliary stones or debris were present and complete the remaining columns as instructed in the General Instructions for this section (VII).

Note: the general instruction statement at the beginning of section VII "… in the absence of these criteria, a clear diagnosis in the patient chart … may be used" does not apply. These criteria must be met for diagnosis.

VII.6 NEUROLOGIC

VII.6.1 CYCLOSPORINE NEUROTOXICITY

Central nervous system disorders believed to be the direct result of toxic levels of cyclosporine. Symptoms often include, but are not limited to: seizures, ataxia, aphasia, cortical blindness, psychotic behavior and/or neuropathy. Other factors such as metabolic imbalances may result in CNS disturbances. These other possible causes should be ruled out before a diagnosis of cyclosporine neurotoxicity is made. Because patients experience cyclosporine toxicity at different blood levels of cyclosporine, a maximum blood level cannot be given.

Completing Form: Check if cyclosporine neurotoxicity occurred and complete the remaining columns as instructed in the General Instructions for this section (VII).

VII.6.2 TACROLIMUS NEUROTOXICITY

Central nervous system disorders believed to be the direct result of toxic levels of tacrolimus. Other factors such as metabolic imbalances may result in CNS disturbances. These other possible causes should be ruled out before a diagnosis of tacrolimus neurotoxicity is made. Because patients experience tacrolimus toxicity at different blood levels of tacrolimus, a maximum blood level cannot be given.

Completing Form: Check if tacrolimus neurotoxicity occurred and complete the remaining columns as instructed in the General Instructions for this section (VII).

VII.6.3 MIGRAINE HEADACHES

Headaches unrelated to organic disease, with a duration of 4 to 72 hours. Migraine pain is characterized by at least two of the following: unilateral location, pulsating quality, moderate to severe intensity, or aggravation by routine physical activity; and at least one associated symptom: nausea and vomiting, or photophobia and phonophobia. Headaches may or may not be precipitated by an aura.

Completing Form: Check if migraine headaches occurred and complete the remaining columns as instructed in the General Instructions for this section (VII).

VII.6.4 SEIZURES

Any seizure believed to be unrelated to cyclosporine or tacrolimus neurotoxicity. Record the first incidence of seizure during the evaluation period regardless of whether or not it was treated. Examples of seizures include grand mal, focal, psychomotor, status epilepticus, etc.

Completing Form: Check if seizure occurred and complete the remaining columns as instructed in the General Instructions for this section (VII).

VII.6.5 STROKE, HEMORRHAGIC

Hemorrhage into the brain caused by a ruptured cerebral artery. May result in sudden loss of consciousness followed by paralysis.

Completing Form: Check if a hemorrhagic stroke occurred and complete the remaining columns as instructed in the General Instructions for this section (VII).

VII.6.6 STROKE, NON-HEMORRHAGIC

Presence of an embolus or thrombus in the brain that occludes a cerebral artery. May result in sudden loss of consciousness followed by paralysis.

Completing Form: Check if a non-hemorrhagic stroke occurred and complete the remaining columns as instructed in the General Instructions for this section (VII).

VII.6.7 HEPATIC ENCEPHALOPATHY

Encephalopathy resulting from liver failure. Characterized by recurrent disturbances of consciousness, impaired intellectual function, neuromuscular abnormalities, metabolic slowing on EEG and elevated serum ammonia levels.

Completing Form: Check if hepatic encephalopathy occurred and document the additional information as defined and as instructed in the General Instructions for this section (VII).

VII.6.7.1 SPECIFY CODE FOR WORST STAGE

If hepatic encephalopathy occurred, refer to the "Stages of Encephalopathy" code list on the page opposite the question. Record the code number that corresponds to the worst stage that occurred during the evaluation period. Asterixis is arrhythmic hand flapping evoked with the arms outstretched and dorsiflexed.

STAGE OF ENCEPHALOPATHY
1 = Lethargy and/or asterixis
2 = Confusion and disorientation
3 = Stupor or coma, but arousable
4 = Deep coma

VII.6.7.2 ONSET DATE OF WORST STAGE

If hepatic encephalopathy occurred, record the date of onset (month/day/year) for the worst stage during the evaluation period. If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99).

VII.6.8 OTHER ENCEPHALOPATHY

Encephalopathy that is due to a cause other than liver failure. Characterized by recurrent disturbances of consciousness, impaired intellectual function, neuromuscular abnormalities, metabolic slowing on EEG and elevated serum ammonia levels.

Completing Form: Check if non-hepatic encephalopathy occurred, specify the type in the space provided, and document the additional information as defined and as instructed in the General Instructions for this section (VII).

VII.6.8.1 SPECIFY CODE FOR WORST STAGE

If non-hepatic encephalopathy occurred, refer to the "Stages of Encephalopathy" code list on the page opposite the question. Record the code number that corresponds to the worst stage that occurred during the evaluation period. Asterixis is arrhythmic hand flapping evoked with the arms outstretched and dorsiflexed.

STAGE OF ENCEPHALOPATHY
1 = Lethargy and/or asterixis
2 = Confusion and disorientation
3 = Stupor or coma, but arousable
4 = Deep coma

VII.6.8.2 ONSET DATE OF WORST STAGE

If non-hepatic encephalopathy occurred, record the date of onset (month/day/year) for the worst stage during the evaluation period. If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99).

VII.7 PSYCHIATRIC (MEDICALLY DIAGNOSED CONDITIONS)

VII.7.1 ALCOHOLISM

Diagnosis of alcoholism made by a physician at the clinical center or by a physician caring for the patient.

Completing Form: Check if alcoholism was diagnosed and complete the remaining columns as instructed in the General Instructions for this section (VII).

VII.7.2 DRUG ABUSE

Diagnosis of drug abuse made by a physician at the clinical center or by a physician caring for the patient.

Completing Form: Check if drug abuse was diagnosed and complete the remaining columns as instructed in the General Instructions for this section (VII).

VII.7.3 TREATED DEPRESSION

Diagnosis and treatment of depression by a physician at the clinical center or by a physician caring for the patient.

Completing Form: Check if depression was diagnosed and treated. Complete the remaining columns as instructed in the General Instructions for this section (VII).

VII.7.4 OTHER PSYCHIATRIC CONDITIONS (excluding cyclosporine or tacrolimus neurotoxicity)

Diagnosis of any other psychiatric condition (excluding cyclosporine or tacrolimus neurotoxicity) that is not already listed in section VII.7 made by a physician at the clinical center or by a physician caring for the patient.

Completing Form: Check if another psychiatric condition was diagnosed, other than those listed in section VII.7, and complete the remaining columns as instructed in the General Instructions for this section (VII).

VII.8 METABOLIC, TOXIC, OTHER

VII.8.1 HYPERCHOLESTEROLEMIA

Blood cholesterol level > 220 mg/dl or medical treatment to lower cholesterol levels.

Completing Form: Check if hypercholesterolemia occurred and complete the remaining columns as instructed in the General Instructions for this section (VII).

VII.8.2 HYPERTRIGLYCERIDEMIA

Blood triglyceride level > 200 mg/dl or medical treatment to lower triglyceride levels.

Completing Form: Check if hypertriglyceridemia occurred and complete the remaining columns as instructed in the General Instructions for this section (VII).

VII.8.3 HYPERKALEMIA (TREATED)

Excessive amount of potassium in the blood that requires medical treatment to lower the potassium level.

Completing Form: Check if hyperkalemia occurred and complete the remaining columns as instructed in the General Instructions for this section (VII).

VII.8.4 CHRONIC ANEMIA

Hemoglobin levels that are consistently < 10 mg/dl. Condition occurs when there is a reduction in the number of circulating red blood cells or a reduction in hemoglobin concentrations.

Completing Form: Check if chronic anemia occurred and complete the remaining columns as instructed in the General Instructions for this section (VII).

VII.8.5 LEUKOPENIA

White blood cell level < 2,000 per cubic millimeter (mm^3) of blood.

Completing Form: Check if leukopenia occurred and complete the remaining columns as instructed in the General Instructions for this section (VII).

VII.8.6 THROMBOCYTOPENIA

Blood platelet level < 80,000 per cubic millimeter (mm^3) of blood.

Completing Form: Check if thrombocytopenia occurred and complete the remaining columns as instructed in the General Instructions for this section (VII).

VII.8.7 AVASCULAR NECROSIS (AVN) - ANY JOINT

Death of areas of tissue or bone surrounded by healthy tissue caused by poor or non-existent blood supply to the area.

Completing Form: Check if avascular necrosis occurred, specify the site in the space provided and complete the remaining columns as instructed in the General Instructions for this section (VII). Note: specification is limited to 30 characters.

VII.8.8 HIP ARTHROPLASTY, EXCLUDING AVN

Surgical formation, reformation, or replacement of the hip joint.

Completing Form: Check if hip arthroplasty was done, specify the reason in the space provided and complete the remaining columns as instructed in the General Instructions for this section (VII). Note: specification is limited to 30 characters.

VII.8.9 KNEE ARTHROPLASTY, EXCLUDING AVN

Surgical formation, reformation, or replacement of the knee joint.

Completing Form: Check if knee arthroplasty was done, specify the reason in the space provided and complete the remaining columns as instructed in the General Instructions for this section (VII). Note: specification is limited to 30 characters.

VII.8.10 FRACTURES / OSTEOPOROSIS

Any bone fracture or diagnosis of osteoporosis that is confirmed by x-ray. Include all fractures, even those that were asymptomatic and diagnosed via a routine x-ray. This may be the case with pathologic fractures. Osteoporosis is demineralization of bone often seen on lumbar/sacral spine films.

Completing Form: Check if any bone fractures occurred or osteoporosis was diagnosed and complete the remaining columns as instructed in the General Instructions for this section (VII).

VII.8.11 GOUT (ANY GOUTY ARTHRITIS ATTACK)

Metabolic disease marked by acute arthritis and inflammation of the joints, caused by excessive uric acid in the blood.

Completing Form: Check if gout occurred and complete the remaining columns as instructed in the General Instructions for this section (VII).

VII.8.12 POUCHITIS

Inflammation of a tissue pocket or sac.

Completing Form: Check if pouchitis occurred and complete the remaining columns as instructed in the General Instructions for this section (VII).

VIII. ANY TREATED INFECTIONS SINCE LAST EVALUATION?

Document all treated infections, including all treated CMV infections, that the patient has had since the previous evaluation period. Use the codes found on the page opposite the question to document the infection site and organism. If a particular infection occurred more than once, list each occurrence separately (one per line). Infections involving more than one site and more than one organism should also be listed separately (one site/organism pair per line).

Completing Form: Check "Yes" if any treated infection occurred since the previous evaluation and document the additional information as defined. Check "No" if no treated infections occurred since the previous evaluation. If there are more infections than spaces provided, check the box at the end of the TREATED INFECTIONS section and document the infection and the corresponding information in the COMMENTS section of the form packet (i.e., end of the LX section). Precede the comment with the keywords "MORE INF."

- Site Code – Refer to the "Infection Sites" code list on the page opposite the question and record the corresponding code number of the infection site. ***If infection site is unknown, record UNK in the space provided.***

- Site Name – Record the name of the infection site, that corresponds to the site code, as it is listed on the page opposite the question. Note: the specified name is limited to 30 characters.

INFECTION SITES

CODE	TYPE	CODE	TYPE
1	Bile Duct	8	Oral
2	Blood	9	Peritoneum
3	Genital	10	Skin
4	Intestinal	11	Upper respiratory tract
5	Liver	12	Urinary tract
6	Lung	13	Wound
7	Meningi/Brain/CNS	14	Other, specify

- Organism Code – Refer to the "Microorganisms" code list on the page opposite the question and record the corresponding code number of the microorganism causing the infection.

- Organism Name – Record the name of the organism, that corresponds to the organism code, as it is listed on the opposite page. Note: the specified name is limited to 30 characters.

MICROORGANISMS

BACTERIAL		FUNGAL		PROTOZOAL		VIRAL	
Code	Type	Code	Type	Code	Type	Code	Type
1	Achromobacter	25	Aspergillus	32	Pneumocystis carinii	35	Adenovirus
2	Acinetobacter	26	Candida	33	Toxoplasma	36	CMV
3	Alcaligenes	27	Cryptococcus	34	Other, specify	37	CMV serology conversions
4	Anaerobes	28	Histoplasma			38	EBV
5	Bacteroides	29	Mucormycosis			39	HIV
6	Citrobacter	30	Torulopsis glabrata			40	HSV
7	Clostridium	31	Other, specify			41	HZV
8	Corynebacterium					42	RSV
9	E. Coli					43	Viral hepatitis A
10	Enterococcus (Strep D)					44	Viral hepatitis B
11	Enterobacter					45	Viral hepatitis B & D
12	Klebsiella					46	Viral hepatitis C
13	Legionella					47	Other, specify
14	Listeria						
15	M. tuberculosis						
16	Neisseria						
17	Pneumococcus						
18	Pseudomonas						
19	Serratia marcescens						
20	Shigella						
21	Staphylococcus aureus						
22	Staphylococcus coagulase negative						
23	Streptococcus (non-enterococcal)						
24	Other, specify						

- Cont. from Prev. Eval. – Place a check in this column if the infection was present during the previous evaluation period and is continuing into this evaluation period. The infection must have been documented on a previous evaluation form.

- If New, Date of Positive Culture – If infection is not continuing from the previous evaluation period, record the date (month/day/year) of the first positive culture from which the infection diagnosis was made. The date recorded should be within the period of time between the previous and this current evaluation. If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99).

IX. COMMENTS

Use this space for any additional information that is pertinent to this evaluation period that has not been recorded elsewhere on the LT/LX/LB form packet.

Completing Form: Check "Yes" if there are comments to be made and write the comments that are pertinent to this evaluation period. Check "No" if there are no comments to be made. If a comment pertains to a specific item in the form, precede the comment with the section and item number, and a few words that begin the item (e.g., "III.1.12 Other immunosuppressives: . . ."). If a comment contains additional biopsies, hospitalizations, medications, graft dysfunction, neoplasia, coronary interventions, or infections that exceeded the space provided in those sections, precede the comment with the keywords MORE BIOP, MORE HOSP, MORE MEDS, MORE GRAFT, MORE NEO, MORE CARD, or MORE INF, respectively. Note: comments are limited to 60 characters per line.

X. LABORATORY DATA

Skip this section if the lab data will be transferred electronically. The lab data recorded here should be the set of test results obtained most recently and prior to the time of this follow-up evaluation. If lab sample analyses were not done at the LTD clinical center, then the most recent set of lab results sent by the patient or the referring physician may be used. Items X.1.1 to X.1.12 are required lab tests and the most recent results must be recorded for each follow-up evaluation. Items X.1.13 to X.1.24 are lab tests that are to be done at least once between years 7 and 11 post-transplant, and are not required for each follow-up evaluation. However, if those lab tests were recently done and the results are available, then record the lab results in any case.

Completing Form: Record the lab test result in the unit and to the decimal place indicated on the form. If the lab test result unit differs from that which is indicated on the form, conversion to the required unit must be made. If the test result shows more decimal digits than required on the form, round to the appropriate number of decimal places (i.e., drop digit if < 5; round up if ≥ 5). If the lab test was done, record the date of the sample (month/day/year), check whether the test result is positive or negative, and record the level or titer where specified. If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99). If the lab test was not done, place a check in the "Not Done" column.

NOTE TO DATA COLLECTOR: If the lab result is outside the "Edit Range," record it and, next to it on the form, indicate that it is a real value by placing your initials (first letter of first, middle, and last names) next to it.

X.1 CLINICAL CHEMISTRY

The following items, X.1.1 to X.1.12, are required lab tests and the most recent results must be recorded for each follow-up evaluation. For item completion instructions refer to the general instructions located in section X. Laboratory Data.

X.1.1 TOTAL BILIRUBIN

1. Normal range: 0.0 to 1.2 mg/dl.
2. Edit range: 0.0 to 76.0 mg/dl.

Completing Form: If test was done, record as _ _._ mg/dl.

X.1.2 DIRECT BILIRUBIN

1. Normal range: 0.0 to 0.3 mg/dl.
2. Edit range: 0.0 to 50.0 mg/dl.

Completing Form: If test was done, record as _ _._ mg/dl.

X.1.3 ALKALINE PHOSPHATASE

1. Normal range for alkaline phosphatase is method dependent, and will vary between clinical centers (usual range: 30 to 530 U/L).
2. Edit range: 30 to 5000 U/L.

Completing Form: If test was done, record as _ _ _ _ U/L.

X.1.4 SGOT (SERUM GLUTAMIC-OXALOACETIC TRANSAMINASE) (or AST)

1. Normal range for SGOT is method dependent, and will vary between clinical centers (usual range: 0 to 40 U/L).
2. Edit range: 0 to 10,000 U/L.

Completing Form: If test was done, record as _ _ _ _ _ U/L.

X.1.5 SGPT (SERUM GLUTAMIC-PYRUVIC TRANSAMINASE) (or ALT)

1. Normal range for SGPT is method dependent, and will vary between clinical centers (usual range: 2 to 56 U/L).
2. Edit range: 1 to 5,000 U/L.

Completing Form: If test was done, record as _ _ _ _ _ U/L.

X.1.6 GAMMA GTP (GLUTAMYL TRANSPEPTIDASE)

1. Normal range for Gamma GTP is method dependent, and will vary between clinical centers (usual range: 6 to 85 U/L).
2. Edit range: 1 to 1,500 U/L.

Completing Form: If test was done, record as _ _ _ _ U/L.

X.1.7 CREATININE

1. Normal range: 0.2 to 1.4 mg/dl.
2. Edit range: 0.1 to 15.0 mg/dl.

Completing Form: If test was done, record as _ _._ mg/dl.

X.1.8 BLOOD UREA NITROGEN (BUN)

1. Normal range: 5.0 to 24.0 mg/dl.
2. Edit range: 1.0 to 180.0 mg/dl.
3. If BUN is not available and urea is available, convert urea to BUN (e.g., BUN = urea ÷ 2.14)

Completing Form: If test was done, record as _ _ _._ mg/dl.

X.1.9 ALBUMIN (BLOOD)

1. Normal range: 3.4 to 5.0 g/dl.
2. Edit range: 1.0 to 6.0 g/dl.

Completing Form: If test was done, record as _._ g/dl.

X.1.10 BLOOD ALCOHOL LEVEL

1. Normal range: 0 mg %
2. Edit range: 1 to 570 mg %

Completing Form: If test was done, record as _ _ _ . _ mg % .

X.1.11 PROTHROMBIN TIME (PT)

1. Record actual laboratory result in seconds under PT.
2. For "control" time, use the actual value if available; otherwise record the highest value given for the "normal" range (i.e., if normal range is 10.9 to 12.8, record 12.8 as the control value).
3. Normal range: 9.5 to 15.9 seconds.
4. Edit range: 9.0 to 50.0 seconds for patient; 10.0 to 15.0 seconds for control value.

Completing Form: If test was done, record as _ _._ seconds for actual PT and for control. If test was done at the LTD clinical center, the "control" results should be obtainable. ***If test was not done at the LTD clinical center and the "control" result is not available, record UNK in the space provided.***

X.1.12 PARTIAL THROMBOPLASTIN TIME (PTT)

1. Record actual laboratory result in seconds under PTT.
2. For "control" time, use actual value if available; otherwise record the highest value given for the "normal" range (i.e. if normal range is 25.0 to 41.0, record 41.0 under control).
3. Normal range: 23.0 to 60.0 seconds.
4. Edit range: 15.0 to 150.0 seconds for patient; 15.0 to 50.0 for control value.

Completing Form: If test was done, record as _ _ _._ seconds for actual PTT and for control. If test was done at the LTD clinical center, the "control" results should be obtainable. ***If test was not done at the LTD clinical center and the "control" result is not available, record UNK in the space provided.***

The following items, X.1.13 to X.1.24, are lab tests that are to be done at least once between years 7 and 11 post-transplant and are not required for each follow-up evaluation. However, if those lab tests were recently done and the results are available, then record the lab results in any case. For item completion instructions refer to the general instructions located in section X.

X.1.13 ALPHA FETO-PROTEIN (AFP)

1. Normal range: 0 to 15 ng/ml.
2. Edit range: 0 to 1,000 ng/ml.

Completing Form: If test was done, record as _ _ _ _ _ ng/ml.

X.1.14 TOTAL CHOLESTEROL

1. Normal ranges for cholesterol vary depending on age and sex, as well as on method for assay (may vary by 15%). Usual range is 30 to 240 mg/dl.
2. Edit range: 30 to 1,000 mg/dl.

Completing Form: If test was done, record as _ _ _ _ mg/dl.

X.1.15 HDL (HIGH-DENSITY LIPOPROTEIN)

1. Normal range: 0 to 100 mg/dl
2. Edit range: 0 to 150 mg/dl

Completing Form: If test was done, record as _ _ _ _ mg/dl.

X.1.16 LDL (LOW-DENSITY LIPOPROTEIN)

1. Normal range: 60 to 180 mg/dl
2. Edit range: 0 to 900

Completing Form: If test was done, record as _ _ _ _ mg/dl.

X.1.17 TRIGLYCERIDES (FASTING)

1. Normal range: 30 to 165 mg/dl
2. Edit range: 0 to 1,500

Completing Form: If test was done, record as _ _ _ _ mg/dl.

X.1.18 GLUCOSE (FASTING)

1. Normal fasting glucose range: 45 to 130 mg/dl.
2. Edit range: 5 to 500 mg/dl.

Completing Form: If test was done, record as _ _ _ mg/dl.

X.1.19 GLYCOSYLATED HEMOGLOBIN (GHB)

1. Normal range for GHB is method dependent, and will vary between clinical centers (usual range: 1.8 % to 8.0 % total hemoglobin)
2. Edit range: 1.0 to 50.0

Completing Form: If test was done, record as _ _ _ . _ % total.

X.1.20 SERUM IRON

1. Normal range: 50 to 175 μg/dl
2. Edit range: 10 to 300 μg/dl

Completing Form: If test was done, record as _ _ _ _ μg/dl.

X.1.21 SERUM FERRITIN

1. Normal range: 5 to 400 ng/ml
2. Edit range: 1 to 5,000 ng/ml

Completing Form: If test was done, record as _ _ _ _ _ ng/ml.

X.1.22 URIC ACID (Blood)

1. Normal range: 2.0 to 8.0 mg/dl
2. Edit range: 0 to 20.0 mg/dl

Completing Form: If test was done, record as _ _ _ . _ mg/dl.

X.1.23 GFR (GLOMERULAR FILTRATION RATE)

GFR is to be done if creatinine clearance was not done.
1. Normal range for this test varies with age (e.g., 20 year old = 110 ml/min).
2. Edit range: 5 to 150 ml/min.

Completing Form: If test was done, record as _ _ _ ml/min.

X.1.24 CREATININE CLEARANCE

Creatinine clearance is a special urine test that helps determine renal function.
1. Normal range: 40 to 140 ml/min (varies with age).
2. Edit range: 5 to 190 ml/min.

Completing Form: If test was done, record as _ _ _ ml/min.

X.2 INFECTION SCREEN

X.2.1 ANTI-HAV IgM

Anti-HAV IgM: The presence of Hepatitis A IgM antibody indicates a recent acute illness. If more than one test was performed during this evaluation period, use the test result closest to the date for this evaluation.

Completing Form: Check whether the anti-HAV IgM test result is positive (pos) or negative (neg) and record the date (month/day/year) of the sample. If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99). If more than one test was performed during this evaluation period, use the test result closest to the date for this evaluation. If the test was not done, place a check in the "Not Done" column.

X.2.2 HBsAg

Hepatitis B surface antigen is associated with the viral surface coat. Its presence in serum usually provides the first evidence of acute hepatitis B infection and implies infectivity of blood. It characteristically appears during the incubation period (4 to 6 weeks after exposure). In acute cases, the antigen usually disappears 1 to 2 months after onset of symptoms. Persistence of HBsAg for more than 6 months may indicate development of a chronic carrier state and may be associated with chronic liver disease. Hepatitis B vaccination does not cause a positive HBsAg.

Completing Form: Check whether the HBsAg test result is positive (pos) or negative (neg) and record the date (month/day/year) of the sample. If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99). If more than one test was performed during this evaluation period, use the test result closest to the date for this evaluation. If HBsAg positive, complete items X.2.2.3 to X.2.2.6. If the test was not done, place a check in the "Not Done" column.

X.2.2.1 HBV DNA

Assay for the presence of hepatitis B viral DNA. HBV DNA is specific and sensitive for the early detection of HBV and may be positive when all other markers are still negative.

Completing Form: Check whether the HBV DNA test result is positive (pos) or negative (neg) and record the date (month/day/year) of the sample. If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99). Record the level obtained for HBV DNA if the test result is positive. ***If the level for a positive result is unknown, record UNK for the level.*** If more than one test was performed during this evaluation period, use the test result closest to the date for this evaluation. If the test was not done, place a check in the "Not Done" column.

X.2.3 ANTI-HBc IgM

Answer only if HBsAg positive. The presence of IgM antibody to hepatitis B core antigen indicates a more recent, acute illness.

Completing Form: Check whether the anti-HBc IgM test result is positive (pos) or negative (neg) and record the date (month/day/year) of the sample. If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99). If more than one test was performed during this evaluation period, use the test result closest to the date for this evaluation. If the test was not done, place a check in the "Not Done" column.

X.2.4 HBeAg

Answer only if HBsAg positive. The presence of hepatitis B envelope antigen (HBeAg) may indicate active viral replication and a highly infectious state. Usually appears within 1 week after appearance of HBsAg and lasts 3-6 weeks. Seroconversion from HBeAg to anti-HBe positivity probably indicates a reduced level of infectivity. Although resolution of the underlying disease generally follows seroconversion, persistence of HbeAg may indicate progression to a carrier state and chronic hepatitis.

Completing Form: Check whether the HBeAg test result is positive (pos) or negative (neg) and record the date (month/day/year) of the sample. If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99). If more than one test was performed during this evaluation period, use the test result closest to the date for this evaluation. If the test was not done, place a check in the "Not Done" column.

X.2.5 ANTI-HBe

Answer only if HBsAg positive. The presence of antibody to hepatitis B envelope antigen indicates a reduced level of infectivity. Resolution of the underlying disease generally follows seroconversion from HBeAg to anti-HBe positivity, however the HBsAg carrier state may persist.

Completing Form: Check whether the anti-HBe test result is positive (pos) or negative (neg) and record the date (month/day/year) of the sample. If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99). If more than one test was performed during this evaluation period, use the test result closest to the date for this evaluation. If the test was not done, place a check in the "Not Done" column.

X.2.6 ANTI-HDV

Answer only if HBsAg positive. Hepatitis delta antigen is a unique, defective RNA virus that can replicate only as a co-infecting agent in the presence of Hepatitis B virus. Delta infection is typically manifest either by unusually severe acute hepatitis, acute exacerbation in chronic HBV carriers, or a relatively aggressive course of chronic Hepatitis B. Hepatitis delta viral antibody appears soon after clinical symptoms but titer is often low and short-lived. Diagnosis of HDV is made by the presence of anti-HDV in HBsAg-positive patients.

Completing Form: Check whether the anti-HDV test result is positive (pos) or negative (neg) and record the date (month/day/year) of the sample. If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99). If more than one test was performed during this evaluation period, use the test result closest to the date for this evaluation. If the test was not done, place a check in the "Not Done" column.

X.2.7 ANTI-HBc

Antibody to hepatitis B core antigen generally appears at the onset of acute clinical illness soon after appearance of HBsAg, with gradually diminishing titer thereafter usually for years and possibly for life. It is also present in virtually all chronic HBsAg carriers and in persons who have been previously infected with HBV.

Completing Form: Check whether the anti-HBc test result is positive (pos) or negative (neg) and record the date (month/day/year) of the sample. If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99). If more than one test was performed during this evaluation period, use the test result closest to the date for this evaluation. If the test was not done, place a check in the "Not Done" column.

X.2.8 ANTI-HBs

Antibody to hepatitis B surface antigen (HBsAg) appears weeks or months after clinical recovery and usually persists for life. Presence of anti-HBs indicates immunity against future HBV infection.

Completing Form: Check whether the anti-HBs test result is positive (pos) or negative (neg) and record the date (month/day/year) of the sample. If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99). If more than one test was performed during this evaluation period, use the test result closest to the date for this evaluation. If the test was not done, place a check in the "Not Done" column.

X.2.9 ANTI-HCV

Hepatitis C viral antibody typically reflects active viral replication and infectivity of host rather than immunity (in contrast to anti-HBs and anti-HBe in HBV infection). May be positive in persons with acute or chronic hepatitis C, HCV carrier state, or past HCV infection.

Completing Form: Check whether the anti-HCV test result is positive (pos) or negative (neg) and record the date (month/day/year) of the sample. If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99). If more than one test was performed during this evaluation period, use the test result closest to the date for this evaluation. If the test was not done, place a check in the "Not Done" column.

X.2.9.1 HCV RIBA

HCV RIBA is a strip immunoblot assay (SIA) for the detection of antibodies to hepatitis C virus and is done to confirm a positive result of the anti-HCV test.

Completing Form: Check whether the HCV RIBA test result is positive (pos), negative (neg), or indeterminate (indet.) and record the date (month/day/year) of the sample. If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99). If more than one test was performed during this evaluation period, use the test result closest to the date for this evaluation. If the test was not done, place a check in the "Not Done" column.

X.2.9.2 HCV RNA (PCR)

Specific and sensitive test that detects and monitors hepatitis C viral replication in the liver. Absence of HCV RNA after therapy is associated with remission.

Completing Form: Check whether the HCV RNA (PCR) test result is positive (pos) or negative (neg) and record the date (month/day/year) of the sample. Record the level obtained for HCV RNA (PCR) if the test result is positive. ***If the level for a positive result is unknown, record UNK for the level.*** If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99). If more than one test was performed during this evaluation period, use the test result closest to the date for this evaluation. If the test was not done, place a check in the "Not Done" column.

X.2.10 ANTI-EBV (VCA) IgG

Epstein-Barr virus (EBV) is a herpes-like virus that causes infectious mononucleosis and is associated with Burkitt's lymphoma and nasopharyngeal carcinoma. VCA (viral capsule antigen) is a more sensitive EBV immunofluorescence antibody test. Positive VCA/IgG antibody titers indicate past infection.

Completing Form: Check whether the anti-EBV VCA/IgG test result is positive (pos) or negative (neg) and record the date (month/day/year) of the sample. If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99). If more than one test was performed during this evaluation period, use the test result closest to the date for this evaluation. If the test was not done, place a check in the "Not Done" column.

X.2.11 ANTI-EBV (VCA) IgM

Epstein-Barr virus (EBV) is a herpes-like virus that causes infectious mononucleosis and is associated with Burkitt's lymphoma and nasopharyngeal carcinoma. VCA (viral capsule antigen) is a more sensitive EBV immunofluorescence antibody test. Presence of VCA/IgM antibody indicates recent primary infection.

Completing Form: Check whether the anti-EBV VCA/IgM test result is positive (pos) or negative (neg) and record the date (month/day/year) of the sample. If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99). If more than one test was performed during this evaluation period, use the test result closest to the date for this evaluation. If the test was not done, place a check in the "Not Done" column.

X.2.12 ANTI-CMV IgG

Cytomegalovirus (CMV) belongs to the herpes virus group and may infect many organ systems. The presence of demonstrable CMV IgG antibody generally indicates past exposure and immunity. A fourfold increase in paired sera IgG titer indicates a recent infection. Criteria for positive or negative results are clinical center specific. Check with the clinical center lab.

Completing Form: Check whether the anti-CMV IgG test result is positive (pos) or negative (neg) and record the date (month/day/year) of the sample. Record the titer obtained for anti-CMV IgG if the result is positive. ***If the titer for a positive result is unknown, record UNK for the titer.*** If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99). If more than one test was performed during this evaluation period, use the test result closest to the date for this evaluation. If the test was not done, place a check in the "Not Done" column.

X.2.13 ANTI-CMV IgM

Cytomegalovirus (CMV) belongs to the herpes virus group and may infect many organ systems. The presence of CMV IgM antibody indicates recent infection. Criteria for positive or negative results are clinical center specific. Check with clinical center lab.

Completing Form: Check whether the anti-CMV IgM test result is positive (pos) or negative (neg) and record the date (month/day/year) of the sample. If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99). If more than one test was performed during this evaluation period, use the test result closest to the date for this evaluation. If the test was not done, place a check in the "Not Done" column.

X.3 IMMUNOLOGY

X.3.1 ANTINUCLEAR ANTIBODY (ANA)

ANA is an antibody that reacts against cellular nuclear material. The test is typically considered positive if ANA is found in a titer with a dilution of > 1:32. However, criteria for positive or negative results may be clinical center specific. Check with the clinical center lab. Positive ANA titers may be found in individuals with chronic hepatitis.

Completing Form: Check whether the ANA test result was positive (pos) or negative (neg) and record the date (month/day/year) of the sample. Record the titer obtained for ANA if the result is positive. ***If the titer for a positive result is unknown, record UNK for the titer.*** If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99). If more than one test was performed during this evaluation period, use the test result closest to the date for this evaluation. If the test was not done, place a check in the "Not Done" column.

X.3.2 ANTI-MITOCHONDRIAL ANTIBODY (AMA)

AMA is an antibody that reacts against cellular mitochondrial material. Criteria for positive or negative results may be clinical center specific. Check with clinical center lab.

Completing Form: Check whether the result was positive (pos) or negative (neg) and record the date (month/day/year) of the sample. Record the titer obtained for AMA if the result is positive. ***If the titer for a positive result is unknown, record UNK for the titer.*** If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99). If more than one test was performed during this evaluation period, use the test result closest to the date for this evaluation. If the test was not done, place a check in the "Not Done" column.

X.3.3 ANTI-MITOCHONDRIAL ANTIBODY (AMA) - M2 SUBTYPE

AMA-M2 subtype is an antibody that reacts against cellular mitochondrial material. Criteria for positive or negative results may be clinical center specific. Check with the clinical center lab.

Completing Form: Check whether the result was positive (pos) or negative (neg) and record the date (month/day/year) of the sample. Record the titer obtained for AMA-M2 subtype if the result is positive. ***If the titer for a positive result is unknown, record UNK for the titer.*** If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99). If more than one test was performed during this evaluation period, use the test result closest to the date for this evaluation. If the test was not done, place a check in the "Not Done" column.

X.3.4 SMOOTH MUSCLE ANTIBODY (SMA)

SMA is an antibody that reacts against smooth muscle tissue. Criteria for positive or negative results may be clinical center specific. Check with the clinical center lab.

Completing Form: Check whether the result was positive (pos) or negative (neg) and record the date (month/day/year) of the sample. Record the titer obtained for SMA if the result is positive. ***If the titer for a positive result is unknown, record UNK for the titer.*** If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99). If more than one test was performed during this evaluation period, use the test result closest to the date for this evaluation. If the test was not done, place a check in the "Not Done" column.

X.3.5 ANTI-LKM (LIVER-KIDNEY MICROSOME)

Anti-LKM is an antibody against cellular ribosomal organelles of the liver and kidney. Liver and kidney microsomes contain cellular RNA and proteins. Criteria for positive or negative results may be clinical center specific. Check with the clinical center lab.

Completing Form: Check whether the result was positive (pos) or negative (neg) and record the date (month/day/year) of the sample. Record the titer obtained for anti-LKM if the result is positive. I***f the titer for a positive result is unknown, record UNK for the titer.*** If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99). If more than one test was performed during this evaluation period, use the test result closest to the date for this evaluation. If the test was not done, place a check in the "Not Done" column.